379h(d)(1)(B)); the applications submitted under section 505(b)(1) and (b)(2) of the Federal Food, Drug, and Cosmetic Act waiver provision (21 U.S.C. 379h(d)(1)(D)); the small business waiver provision (21 U.S.C. 379h(d)(1)(E)); and to requests for refunds of fees if an application or supplement is withdrawn after filing (21 U.S.C. 379h(a)(1)(G)); as well as waivers, reductions, or refunds requested on any other basis except fees exceeding the cost. (See § 5.20(h)(1) for the authority to reconsider any user fee decisions made by the Chief Mediator and Ombudsman, the Deputy Chief Mediator and Ombudsman, and/or the former Deputy User Fee Waiver Officer prior to July 1, 1999.) These officials may not further redelegate this authority.

### § 5.109 Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under § 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) regarding the issuance of written notices.

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(2) The Director and Deputy Director, Office of Compliance, CDER.

(3) The Director and Deputy Director, Division of Labeling and Nonprescription Drug Compliance, Office of Compliance, CDER.

(4) The Director and Deputy Director, Division of Manufacturing and Product Quality, Office of Compliance, CDER.

(5) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

(6) The Associate Director for Medical Policy, and the Director and Deputy Director, Division of Scientific Investigations, Office of Medical Policy, CDER.

(7) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), the Director and Deputy Directors, Office of Compliance and Biologics Quality (OCBQ), CBER, and the Directors, Division of Case Management, Division of Inspections and Surveillance, and Division of Manufacturing and Product Quality, OCBQ, CBER.

(8) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Directors of the Office of Device Evaluation, CDRH.

(9) Regional Food and Drug Directors.

(10) District Directors.

(b) These officials may not further redelegate this authority.

## Subpart D—Biologics; Redelegations of Authority

### § 5.200 Functions pertaining to safer vaccines.

(a) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER) are authorized to perform the functions of the Commissioner of Food and Drugs (Commissioner) under part C, subtitle 2 of title XXI of the PHS Act (42 U.S.C. 300aa–25 *et seq.*), as amended, and the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa–1 note), as amended hereafter, as follows:

(1) Section 2125 of the PHS Act (42 U.S.C. 300aa–25)–Recording and reporting of information.

(2) Section 2127 of the PHS Act (42 U.S.C. 300aa–27)–Mandate for safer childhood vaccines.

(3) Section 2128 of the PHS Act (42 U.S.C. 300aa–28)–Manufacturer recordkeeping and reporting.

(4) Section 312 of the National Childhood Vaccine Injury Act of 1986–Related studies (42 U.S.C. 300aa–1 note), except that the authority to provide for notice and opportunity for public hearing on the review of vaccines and related illnesses and conditions under sections 312(a) and (d) of the National Childhood Vaccine Injury Act of 1986 is not redelegated by the Commissioner.

(5) Section 313 of the National Childhood Vaccine Injury Act of 1986–Study of other vaccine risks (42 U.S.C. 300aa–1 note), except that the authority to provide for notice and opportunity for public hearing on the establishment of

guidelines regarding the risks to children of certain vaccines under section 313(a)(1)(B) and (b) of the National Childhood Vaccine Injury Act of 1986 is not redelegated by the Commissioner.

(6) Section 314 of the National Childhood Vaccine Injury Act of 1986–Review of warnings, use instructions, and precautionary information (42 U.S.C. 300aa–1 note).

(b) These officials may not further redelegate these authorities.

### § 5.201 Redelegation of the Center for Biologics Evaluation and Research Director's program authorities.

(a) The following officials are authorized to perform all the functions of the Director, Center for Biologics Evaluation and Research (CBER) with regard to program authorities for their respective areas:

(1) Deputy Directors, CBER.

(2) Associate Directors, CBER.

(3) Office Directors, CBER.

(4) Division Directors, CBER.

(b) These officials may not further redelegate these authorities.

### § 5.202 Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses, suspension of licenses, or revocation of licenses and certain notices of revocation of licenses.

(a) The Director and Deputy Directors, Center for Biologics Evaluation and Research are authorized to issue:

(1) Notices of opportunity for a hearing on proposals to deny approval or filing of applications for biologics licenses under § 601.4(b) of this chapter.

(2) Notices of opportunity for a hearing on proposals to revoke biologics licenses under § 601.5(b) of this chapter.

(3) Notices of revocation, at the manufacturer's request, of biologics licenses under §§ 601.5(a) and 601.8 of this chapter.

(4) Notices of revocation when the manufacturer has waived the opportunity for hearing under § 601.7(a) of this chapter.

(5) Notice of biologics license suspensions under § 601.6 of this chapter.

(b) These officials may not further redelegate these authorities.

### § 5.203 Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.

(a) The following officials are authorized to issue licenses under section 351 of the PHS Act (42 U.S.C. 262) for the propagation or manufacture and preparation of biological products as specified in the PHS Act, and to revoke such licenses at the manufacturer's request:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(2) Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

(b) These officials may not further redelegate this authority.

### § 5.204 Notification of release for distribution of biological products.

(a) The following officials are authorized to issue written notices of release for distribution of licensed biological products under subchapter F (parts 600 through 680.31) of this chapter:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(2) The Director and Deputy Directors, Office of Compliance and Biologics Quality (OCBQ), CBER.

(3) The Director and Deputy Director, Division of Manufacturing and Product Quality, OCBQ, CBER.

(b) These officials may not further redelegate this authority.

## Subpart E—Food and Cosmetics; Redelegations of Authority

### § 5.300 Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) under sections 409 and 721 of the act (21 U.S.C. 348 and 379e) regarding the issuance of notices of filing (including notices of extension of, or reopening of, the comment period), and of voluntary withdrawal, of petitions